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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,823	08/22/2001	Corrado Fogher	4161-14	8610

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/743,823	FOGHER, CORRADO	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 3, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98-117 and 124-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *98-111,124-131 and 138-145* is/are allowed.

6)☒ Claim(s) *112-117,132-137 and 146-151* is/are rejected.

7)☒ Claim(s) *117,137 and 151* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on October 3, 2006 been entered.

Claims 1-97 and 118-123 are cancelled.

Claims 112-117 are withdrawn.

Claims 124-151 are new.

Claims 98-117 and 124-151 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Claims 98-111 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 112-117, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement between the claimed products and methods for making and/or using said products is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the

instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 114-117, 134-137 and 148-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods for the production of human lactoferrin-containing flours, functional food containing human lactoferrin, including functional foods selected from the group consisting of vegetal milks, fruit juices, fruit homogenized foods and vegetable homogenized foods, and transgenic plants as nutraceuticals.

With respect to lactoferrin-containing flours, functional foods and nutraceuticals, the specification discloses in general that plants can be used as functional foods, i.e. foods that are genetically modified so as to be enriched from a nutritional point of view, and in case assuming important properties as a natural drug, and that the heterologous protein expression in transgenic plants may enrich a vegetable nutrient which thus becomes a nutraceutical, i.e., a nutriment having a pharmaceutical value (page 3). The specification also discloses that since transgenic

plants can be used a nutraceuticals and therefore directly intaken as alimentary products, they may also be used for the production of protein flours (page 20). The specification additionally discloses that the production of functional foods containing proteins produced by the disclosed transgenic plants as one objective of Applicant's invention, and the use of transgenic plants as nutraceuticals as another (page 24). The specification does not disclose any specific examples of functional foods containing proteins produced by the disclosed transgenic plants.

The claimed invention is not enabled because the functional effect of plant material expressing a recombinant therapeutic protein as a food is unpredictable, since the functional effect of a recombinant therapeutic protein may be altered by a variety of factors such as its environment, mode of administration and target population, such that the functional effect of such any such food must be determined empirically.

See, for example, Mollet B. et al. (Functional foods: at the frontier between food and pharma. Curr Opin Biotechnol. 2002 Oct;13(5):483-5), who teach that functional foods, also referred to as 'nutraceuticals' or 'pharmaceutical foods', "can be regarded as functional if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either improved state of health and well-being and/or reduction of risk of disease" (page 483 first paragraph).

See also, for example, Roberfroid M.B. (Concepts and strategy of functional food science: the European perspective. Am J Clin Nutr. 2000 Jun;71(6 Suppl):1660S-4S; discussion 1674S-5S. Review), who teaches that a functional effect of a food that can be defined must also be demonstrated in relevant models, and that the experimental part of functional food development should conclude with a new hypothesis on the relevance of the functional effect to

human health, which hypothesis must be tested in strictly designed nutritional studies involving carefully chosen volunteers, the demonstration of effects accompanied by a safety assessment, an absolute prerequisite for functional food development (page 1661S column 2).

See additionally, for example, Roberfroid M.B. (Concepts in functional foods: the case of insulin and oligofructose. J Nutr. 1999 Jul;129(7 Suppl):1398S-401S. Review), who teaches "a food for which a claim has been authorized" as a practical and simple definition of a "functional food" (abstract), and that "a functional food should have a relevant effect on well-being and health or result in a reduction in disease risk" (page 1398S column 2 first full paragraph). Roberfroid M.B. also teaches that the documentation of the potential health benefits of these foods requires scientific evidence that must be evaluated in terms of health claims (abstract), and that while a food product may be made functional by adding a component that is not normally present in the food but for which beneficial effects have been demonstrated, the demonstration of the beneficial effect of the food product requires a strict scientific approach for which a strategy can be proposed (page 1398S column 2 through page 1399S first column). Roberfroid M.B. additionally teaches that both functional effects and disease risk reduction require the demonstration of an effect in humans based on nutritional studies designed according to protocols and evaluation criteria which are not necessarily those presently used in clinical studies for drug development (page 1399S column 2).

In the instant case Applicant has not provided any of the guidance considered necessary to define a food as functional or nutraceutical. Applicant has not demonstrated any specific beneficial effect to any particular target function in the body for any type of transgenic plant, or for any type of food product derived therefrom, beyond adequate nutritional effects, in a way that

is relevant to either improved state of health and well-being and/or reduction of risk of disease, as suggested by Mollet B. et al. Applicant has not defined a specific functional effect of any type of transgenic plant, or of any type of food product derived therefrom, or demonstrated a specific functional effect in relevant models, or proposed or tested in strictly designed nutritional studies involving carefully chosen volunteers a new hypothesis on the relevance of the functional effect to human health, accompanied by a safety assessment, as suggested by Roberfroid M.B. (2000). Applicant has not demonstrated any relevant effect on well-being and health or result in a reduction in disease risk or any type of transgenic plant, or for any type of food product derived therefrom, or provided any scientific evidence evaluated in terms of health claims, or demonstrated any effect in humans based on nutritional studies designed according to appropriate protocols and evaluation criteria, as suggested by Roberfroid M.B. (1999).

Given the unpredictability of the functional effect of plant material expressing a recombinant therapeutic protein as a food, the absence of working examples and other forms of guidance, and the breadth of the claims which encompass foods of undefined and undisclosed nutraceutical function, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 112-113, 132-133 and 146-147 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 112-113, 132-133 and 146-147 require

extracting human lactoferrin from the seeds of the transgenic plants of claims 108, 128 and 142,

but the claims do not recite any technical steps by which the extraction may be accomplished.

Allowable Subject Matter

Claims 98-111, 124-131 and 138-145 are allowed.

Double Patenting

Claim 117 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 108. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is also noted that this objection is based on the interpretation of the claim limitation "as a nutraceutical" as recitation of an inherent property or intended use of the transgenic plant claimed.

Claim 137 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 128. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is also noted that this objection is based on the interpretation of the claim limitation "as a nutraceutical" as recitation of an inherent property or intended use of the transgenic plant claimed.

Claim 151 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 142. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is also noted that this objection is based on the interpretation of the claim limitation "as a nutraceutical" as recitation of an inherent property or intended use of the transgenic plant claimed.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

12/11/06